

Elite™

Troubleshooting Guide



MEDGRAPHICS
Cardiorespiratory Diagnostics

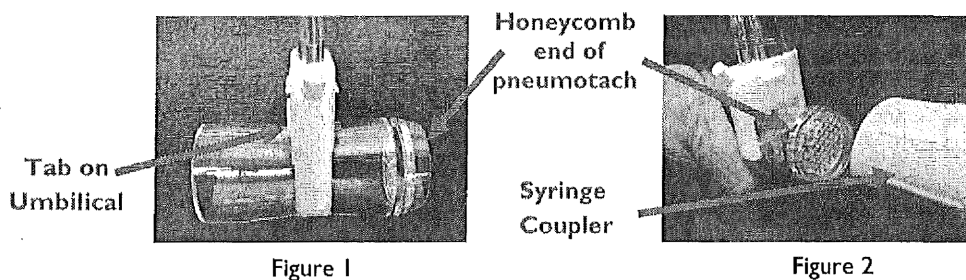


Elite™ Troubleshooting Guide

DAILY CALIBRATION TROUBLESHOOTING

Pneumotach Calibration Errors

- Is the umbilical connected to the pneumotach in the correct orientation? (see Figure 1)
- Is the pneumotach correctly positioned in relation to the syringe (i.e., is the honeycomb end of the pneumotach in the syringe)? (see Figure 2)



- Zero the flow, click Start and perform one withdrawal and one injection. Click Stop. Click Start and perform a full calibration. During each withdraw and inject ensure there is a pause between syringe strokes.
- **Do Not** click Reset  between calibrations.
- If pneumotach calibration failures persist see FLOW TROUBLESHOOTING section.

Box transducer Errors

- No waveform on the screen during calibration or Transducer gain fails high. Ensure box door is sealed, compressed air cylinder is > 500 psi and regulator is delivering 20 psi.
- Zero offset fails. Make sure when entering the *pleth calibration* screen the transducer output is displaying zero. If not, use the box pressure potentiometer to set the box transducer output to zero. (see Figure 3)
- Calibration pump frequency fails. - Increase or decrease pump frequency using the potentiometer located on top of the plate to which the GC column is connected. Pump frequency range is 1.2-1.5 Hz. (see Figure 4)



Figure 3

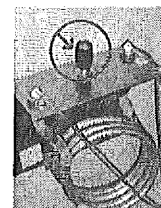


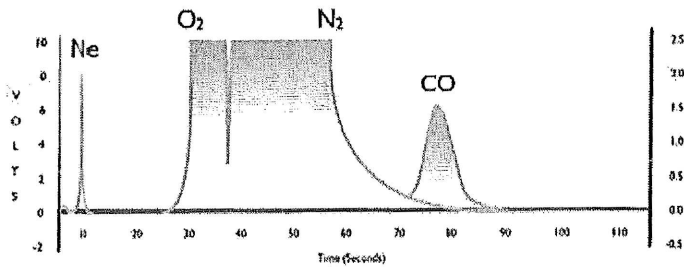
Figure 4

Mouth Transducer or MIP/MEP Transducer

- Transducer gain fails. Ensure that DLCO gas cylinder valve is open, pressure is >500 psi in DLCO cylinder and regulator is delivering 135 psi.

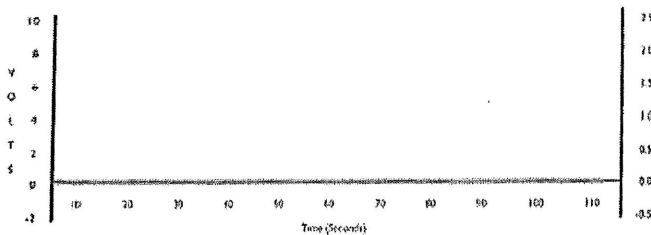
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DIFFUSION TRACE TROUBLESHOOTING



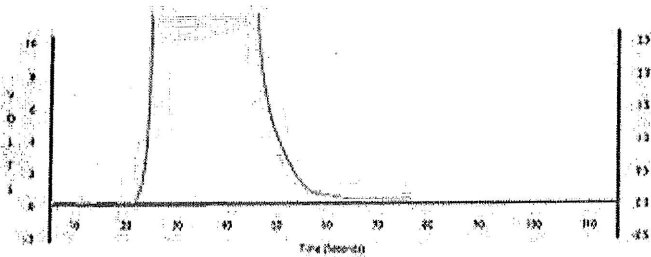
Acceptable Tracing

- Ne between 8.5-9.5 volts
- Ne tracing within 10 seconds
- A new GC column will trace a division between O2 and N2
- There should be 15 seconds between the end of the N2 peak and the CO peak.
- The entire tracing takes approximately 90 seconds.



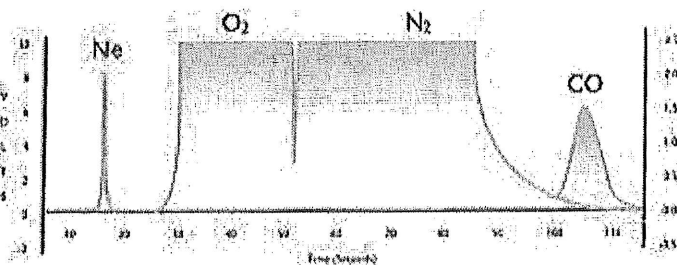
No Helium Flow

- Ensure Helium cylinder is open
- Ensure >500 psi in Helium cylinder
- Ensure Helium regulator is delivering 10-25 psi.
- Ensure Helium is READY in Breeze Suite



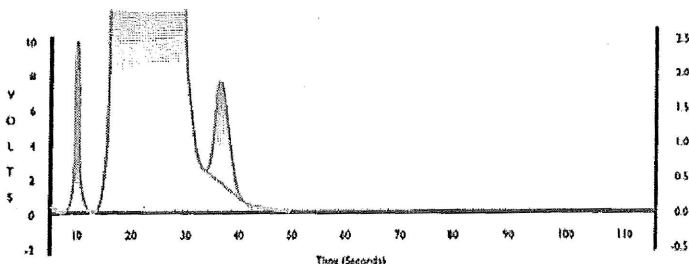
No Diffusion Gas Analysis

- Ensure DLCO gas cylinder is open
- Ensure DLCO gas cylinder is >500 psi.



DLCO trace is too long

- Increase Helium psi



DLCO Trace is too short

- Decrease Helium pressure
- If Helium is <12 psi, replace GC column.



The MedGraphics Elite Troubleshooting Guide is Part No. 142185-001 Rev A.

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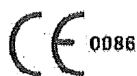
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European Medical Device Directive

Devices are compliant with the European Medical Directive (93/42/EEC) regarding safety and EMC.

only do Shape tables w/ new umbilical or flow board
saves as lyp

Quality Control Procedures

Tool bar must be present
to test. Icon: Test mode
pneumotach

Do complete calibration of system.

Open a new patient. Use the new patient icon or File, new, patient.

Place a check in the box marked 'BTPS correction off'. (Click yes to warning message)

Add last name and ID in appropriate boxes.

Select add visit.

Review "4 graphs"

FVC QC:

(No info has to be put in)
- forced vital capacity

Select FVC tab at the bottom of the screen.

Connect pneumotach to syringe.

Zero pneumotach by clicking on zero icon.

Do 5-6 efforts with syringe while varying flow speeds.

Check the values in the FVC row. All values must be within 90ml of 3 liters and within 90ml of each other. (2.91 - 3.09)

Volume-time graph selected by clicking *prep
Red Error boxes Normal for QC

DLCO QC:

Select DLCO tab at the bottom of the screen.

Ensure helium pump is ready. If not, wait until timer displays the green 'ready'.

Click on the analyze icon at the top of the screen.

Wait for DLCO analysis to complete.

When DLCO analysis passes, connect the pneumotach and syringe to the patient circuit in the head of the system.

Zero pneumotach.

Withdraw the syringe and place thumb exactly on the 2 liter mark on the syringe shaft.

Hit space bar 3 times and withdraw syringe completely.

The lockout time of 20 seconds will begin.

"NOTE" Hold syringe straight and secure in the patient circuit.

After the lockout time is complete, inject syringe completely.

The effort analysis will now draw on the screen.

Refer to the quality control spec sheet to check values.

N2 QC:

when finished Helium gas will be flushed by Regulator
IF VA Low replace patient circuit

Select FRC tab at the bottom of the screen.

Place umbilical clip in the calibration port in the head of the system.

Press space bar to calibrate nitrogen.

FRC (N₂)

*Blow w/ syringe to get DKO gas flushed

Drop gain to
Increase Peak% while
adjusting needle valve

If unit fails "open up needle valve turn counter-clockwise"
(small turns) Turn half-hour to an hour turn

Hit spacebar
after every
inhale/exhale

if not
passing

"Lung diffusion by CO₂"

*Can back flow umbilical

check BTPS box or #'s will be high

use O₂ + backflush "3 off" make sure
(10L) (lines) lines are
reset

(Push far
enough)

*If Analyze
waveform to long
increase helium

helium
is inversely
affected by Neon

helium ↑ Neon ↓
Neon ↑ helium ↓

Fast

Fast withdrawal

Looking for IVC + VA within
Range

Mark must be on top to ensure
DLCO gas taken in correctly
by patient

When calibration passes, connect umbilical with the pneumotach attached to patient circuit in the head of the system.

Withdraw syringe and place thumb exactly at the .5 mark on the syringe shaft.

Hit spacebar to start trace. Ensure a straight line is being drawn. After 5 seconds, hit space bar again.

Begin syringe tidal breathing simulating a normal breathing rate.

After 4 breaths, the distal scissor valve will lock out. Continue simulating a normal breathing rate. After the N2% falls below 1.7% for 2 consecutive breaths, the distal piston will open.

Check the value in the FRC column. It should be 2.34- 2.86 Liters.

2.60 Liter target +/- 10%.



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Informational Product Bulletin

Applicable To:

☒ MGC Employee ☒ Distributor ☒ Customer

Product(s): Elite Series, Profiler Series, Ultima Series, 1085D, PF/Dx

Date: February 25, 2006

Subject: Syringe Quality Control

PURPOSE: The Syringe Quality Control Specifications have been standardized for all of the systems. The new specifications are detailed below.

PROCEDURE/INSTRUCTIONS:

BreezeSuite & BreezePF Software - In Patient Information, check the "BTPS Correction Off" box

Breeze 1.9 Software - In F5 Setup of testing screen, switch to "Testing Syringe"

Assumptions: Using 3 liter syringe & syringe deadspace is 100 ml

SPIROMETRY

Perform 5-6 FVC efforts

Vary flows: some slow efforts, some medium, some fast

Specification: VC $\pm 3\%$

Target = $3.00 \pm 3\%$

Low Range 2.91

High Range 3.09

NITROGEN WASHOUT

Place thumb at exactly 500 ml mark on syringe plunger

Tidal breathe at 500 ml mark until switched into 100% O₂

Respiratory rate of ~12-16 bpm

Specification: FRC $\pm 10\%$

Target FRC = Syringe Volume + Syringe Deadspace

Target FRC = $2.50 + .100$

Target FRC = $2.60 \pm 10\%$

Low Range = Target FRC * .90 ($2.60 * .90 = 2.34$)

High Range = Target FRC * 1.10 ($2.60 * 1.10 = 2.86$)

DIFFUSION

NOTE: Systems using Breeze 1.9 software must change temperature and barometric pressure in DLco F5 Setup menu to 37 & 760 respectively. Ensure that the environmental settings are reset after performing DLco syringe study or patient results will be affected.

BreezePF & Breeze 1.9 software: Change Lock-out Time to 20 seconds in F5 Setup
Perform DLco syringe test same as testing patient

Specifications

DLCO Quality Control Test is completed using a 3 Liter syringe, setup so that it contains 1 liter of room air (starting the syringe QC with either the collar or thumb positioned exactly at the 2 liter mark). No tidal breathing will be needed for DLCO QC Test.

Test is completed with BTPS correction turned off.

This table is based on a syringe dead space of 100ml.

Target IVC = 2.0 liters +/-5%

Target VA = 3.0 liters +/-8%

Target DLco = +/-0.5

Measured IVC should be 1.90 to 2.10. To find Target VA, find Measured IVC in second column. Target VA and Min/Max values will be displayed to the right of the Measured IVC.

Syringe Stroke	Measured IVC	Target VA	Minimum VA	Maximum VA
2.0	1.90	2.83	2.60	3.06
2.0	1.91	2.84	2.61	3.07
2.0	1.92	2.86	2.63	3.09
2.0	1.93	2.88	2.65	3.11
2.0	1.94	2.90	2.67	3.13
2.0	1.95	2.91	2.68	3.14
2.0	1.96	2.93	2.70	3.16
2.0	1.97	2.95	2.71	3.19
2.0	1.98	2.97	2.73	3.21
2.0	1.99	2.98	2.74	3.22
2.0	2.00	3.00	2.76	3.24
2.0	2.01	3.02	2.78	3.26
2.0	2.02	3.03	2.79	3.27
2.0	2.03	3.05	2.81	3.29
2.0	2.04	3.07	2.82	3.32
2.0	2.05	3.09	2.84	3.34
2.0	2.06	3.10	2.85	3.35
2.0	2.07	3.12	2.87	3.37
2.0	2.08	3.14	2.89	3.39
2.0	2.09	3.16	2.91	3.41
2.0	2.10	3.17	2.92	3.42

Please visit our website www.medgraphics.com for additional product support via the answer book.

Calibration Procedures

Calibration: Click on Breeze Suite icon.

Turn on helium pump and nitrogen pump (if applicable). This will allow proper warm-up time for Quality Control procedure.

Click on 'Calibration icon'

Note: Refer to toolbar for instructions.

Pneumotach calibration:

Connect pneumotach to umbilical.

Connect pneumotach to calibration syringe.

Zero flow transducer.

Hit space bar or start button to start calibration.

Follow withdraw and inject prompts until calibration is completed.

Plethysmography calibration:

Select pleth tab at top of screen.

Turn inflate/deflate switch on side of the box to 'inflate'.

Close door and allow the seal to inflate. Allow 30 – 60 seconds for equilibration.

Hit space bar or click on zero icon to zero box and mouth pressure transducers.

Hit space bar or box calibration icon to activate calibration pump.

After pump runs, hit space bar or mouth cal icon to activate the dead weight assembly to pressurize the mouth pressure transducer.

MIP/MEP calibration:

Select MIP/MEP tab on top of the screen.

Hit space bar or click on zero icon.

Hit space bar or click on start icon.

Print a copy of the calibration report.